PSY3

RISK OF CARDIOVASCULAR, GASTROINTESTINAL, AND RENAL ADVERSE EVENTS ASSOCIATED WITH DICLOFENAC IMMEDIATE AND EXTENDED RELEASE DRUG PRODUCTS: AN OBSERVATIONAL STUDY USING US CLAIMS DATA

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OBJECTIVES: Safety studies have shown that risks associated with use of non-steroidal anti-inflammatory drugs (NSAIDs) are related to dose and release form; however, there is little US evidence. This study assessed the relationships between diclofenac dose and release form on gastrointestinal (GI), cardiovascular (CV), and renal events using US health care claims. **METHODS:** The MarketScan© Commercial Claims and Encounters database (2008-12) was used to analyze the risks of GI (upper GI bleed/perforation [UGIB], lower GI bleed [LGIB]), CV (myocardial infarction [MI], stroke, and congestive heart failure [CHF]), and renal events by diclofenac dose category relative to no current NSAID use and extended/delayed release (ER) relative to immediate release (IR) form among new adult users of diclofenac. Patients with prior history of GI, CV or renal disease were excluded. Hazard ratios (HRs) were estimated using multivariable Cox regression models with total daily dose (TDD) and release form as time-dependent covariates. **RESULTS:** In total, 851,549 diclofenac users (57% female; median age 50 years) met the initial study inclusion criteria. At diclofenac initiation, median TDD was 150mg (range: 1-400mg) and most (88.25%) prescriptions were ER. The HRs (95% CIs) for TDD >150mg (vs no current exposure) were: UGIB: 3.48 (2.25-5.37) for ER and 2.59 (1.55-4.33) for IR; LGIB: 1.58 (1.31-1.91) for ER and 1.37 (1.11-1.70) for IR; MI: 1.10 (0.74-1.62) for ER and 1.02 (0.66-1.60) for IR; stroke: 1.08 (0.90-1.31) for ER and 1.09 (0.88-1.34 for IR); CHF: 1.39 (1.14-1.70) for ER and 1.38 (1.10-1.74) for IR; and renal failure: 2.25 (1.84-2.76) for ER and 2.05 (1.60-2.61) for IR. **CONCLUSIONS:** In an analysis of US health care claims, increased risks of certain adverse events were associated with higher doses compared with no current use and with ER compared with IR form among new users of diclofenac with no prior history of the event.

PSY4

LESSONS LEARNED FROM THE PILOT INTRODUCTION OF PEGINESATIDE, A THIRD GENERATION ERYTHROPOIESIS STIMULATING AGENT

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OBJECTIVES: Peginesatide is a peptide-based erythropoietin receptor agonist withdrawn after anaphylaxis/hypotension events (AHEs) occurred in 2012 and 2013. Centers affiliated with a phase IV study conducted by the largest dialysis organization (LDO) in the United States treated 20,000 patients and unaffiliated centers treated 5,000 patients. Our objective was to summarize AHEs associated with peginesatide during the phase IV study. **METHODS:** The pilot included manufacturer-supplied nurse monitors at 10 LDO sites who prospectively evaluated efficacy, safety, and logistics of peginesatide. Interim analyses in January 2013 were favorable. A protocol change in October required that no other intravenous medication be administered within one hour of peginesatide, after 8 anaphylaxis hypotension events from the pilot occurred. The pilot was expanded to 348 of the LDO's 2100 sites. Centers unaffiliated with the pilot also provided peginesatide without monitoring. We compared timeliness, quantity, and characteristics of anaphylaxis-hypotension events from each setting. **RESULTS:** Twenty eight AHEs were from the phase IV study (1.4 per 1,000 patients) and 10 were from unaffiliated centers (1.4 per 1,000 patients). Centers in the pilot reported events more rapidly (median days = 46 versus 81). Minutes to onset was similar (median = 3 versus 5). AHEs from the pilot were more often grade 4 severity or fatal (44% versus 10%) or associated with cardiorespiratory arrest (29% versus 0%). On February 11 and 12, 2013, three fatalities and two grade IV events occurred at four pilot sites. An unplanned analysis identified a fatality rate of 0.3/1000-treated patients in the pilot study. Peginesatide was withdrawn. **CONCLUSIONS:** Absent timely and comprehensive conduct of the LDOs pilot study , the safety signal may have gone unnoticed for years. Prospectively-monitored phase IV studies could enhance detection of rare serious adverse events of novel medicines, including biologicals.

PSY5

THE VALIDITY OF ALGORITHMS FOR IDENTIFYING SUSPECTED AND CONFIRMED HEPARIN-INDUCED THROMBOCYTOPENIA

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OBJECTIVES: The aim of this study was to develop and compare three algorithms for identifying heparin-induced thrombocytopenia (HIT) using gold standard measures of clinically suspected and actual HIT. **METHODS:** We identified 45,096 inpatients exposed to heparin from 2006 to 2011 at an urban academic medical center. Three algorithms were examined: (A) initiation of direct thrombin inhibitor (DTI) treatment and a diagnostic test ordered more than 4 days after exposure to heparin; (B) algorithm A plus presence of ICD-9-CM code 287.4, 287.5, or 289.84; and (C) algorithm A plus presence of ICD-9-CM code 289.84. The data were collected from medical and billing records for patients (n=39) identified by algorithm A and a random sample (n=250) of patients who did not meet the algorithm's definition. Algorithms B (n=24) and C (n=6) were subsets of algorithm A. The performance of the algorithms was computed based on the ascertainment of confirmed/suspected HIT by clinicians. Suspected HIT cases were tested for HIT antibodies and administered DTI to treat HIT. **RESULTS:** The positive predictive values (PPV) for confirmed HIT were 30.77%, 37.50% and 50% for algorithms A, B and C, respectively (P=0.547). However, the PPV was 100% for suspected HIT for all three algorithms. The differences in sensitivity between the algorithms A, B, and C for confirmed (100% vs. 75% vs. 50%; P=0.024) and suspected (100% vs. 61.54% vs. 40%; P<0.001) HIT were statistically significant. **CONCLUSIONS:** These findings suggest that algorithms based on medical and billing records can be used to identify patients with suspected HIT.

PSY6

MAJOR EARLY COMPLICATIONS FOLLOWING BARIATRIC SURGERY: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: This systematic review and meta-analysis studied major surgical complications, including pulmonary embolism (PE), myocardial infarction (MI), and leak, resulting from different bariatric surgery procedures, using recently published data and appropriate meta-analysis techniques. **METHODS:** Surgeries considered were Roux-en-Y gastric bypass (RYGB), adjustable gastric banding (AGB), and sleeve gastrectomy (SG). Literature searches of PubMed, Embase, Scopus, and the Cochrane Library databases between 2003 and September 2014 were performed. Articles were screened for exclusion and inclusion criteria before data extraction. Quality of evidence was assessed and each article was rated for quality. Post-surgery complication rates of PE, MI, and leak were stratified by time points (≤30 day and >30 day) and synthesized by Bayesian random-effects meta-analyses. In cases in which both randomized control trials (RCTs) and observational studies (OBSs) were available, RCTs and OBSs were analyzed separately. **RESULTS:** Our study included 61 articles (60 OBSs, 1 RCT) and 108,396 patients with a mean age of 44.3 years and mean pre-surgery body mass index (BMI) of 46.5 kg/m2. Only one article recorded a leak following RYGB at ≥30 days, reporting 2 in 218 patients. The ≤30 day mean rate of complications and the 95% credible intervals (in brackets) for OBSs are presented. The leak rate for RYGB was 0.91% [0.56%, 1.35%] and for SG was 0.72% [0.01%, 2.54%]. The MI rate for RYGB was 0.06% [0.02%, 0.15%] and higher for AGB 1.05% [0%, 2.68%]. Incidence of PE for all procedures was 0.35% [0.14%, 0.74%], with AGB having the lowest rate (0.11%), followed by SG (0.54%) and RYGB (0.69%). **CONCLUSIONS:** This study suggests that the risk of PE, MI, and leak following bariatric surgery is low. However, these are serious, life-threatening adverse events with non-negligible coincidence whose risk should be effectively communicated to patients when surgical treatment is considered.

PSY7

ESTIMATING QUALITY OF LIFE OF PATIENTS WITH LIPODYSTROPHY

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OBJECTIVES: Lipodystrophy syndromes (LD-S) are rare syndromes characterized by selective loss of fat and severe metabolic abnormalities. Based on patient accounts, LD-S have a significant impact on quality of life (QOL). This is the initial organized effort to estimate the QOL for individuals with LD-S based on the patient's self-reported findings. **METHODS:** LD Connect, launched in January 2014, is a global registry for the lipodystrophy community, including patients and caregivers. This registry collects self reported data from members who join the effort on the registry website (www.ldconnect.org). We analyzed QOL data collected from individuals who self-identified as having lipodystrophy through December 9, 2014. The QOL questionnaire included items from the Patient Reported Outcomes Measurement Information System (PROMIS) short forms, questions on financial impact and impact of pain. We estimated T-scores for the participants where a T-score of 50 represents the average score for the general population with a standard deviation (SD) of 10. EQ-5D scores were also estimated from PROMIS global health items. **RESULTS:** Out of 126 participants, 48% responded to the QOL questionnaire. Among responders 97% were females, 84% had partial LD, and 51% were from the US. T-scores for physical and mental health were 43.14 and 41.90 (SD 9.05 and 9.38, respectively). T-scores for social isolation, social support, and stigma were 51.57, 52.91, and 55.30, respectively. The estimated average EQ-5D score for LD-S was 0.67; much lower than the average EQ-5D of a general population (0.866). Patients also reported a minimal to moderate financial impact of lipodystrophy, with 27% reporting that costs affected their decision to seek care for lipodystrophy. **CONCLUSIONS:** LD-S patients reported having some impairment in quality of life on domains of physical health, and mental health, social isolation, and stigma compared to general population. Further work is required to characterize the extent of impairment.

PSY8

COMPARISON OF DISEASE STATUS AND OUTCOMES OF PATIENTS WITH ANKYLOSING SPONDYLITIS (AS) RECEIVING ADALIMUMAB OR ETANERCEPT MONOTHERAPY IN THE UNITED STATES (US)

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OBJECTIVES: To compare the disease status and outcomes of patients with AS receiving adalimumab and etanercept monotherapy in the US. **METHODS:** A medical chart-review of AS patients was conducted to collect de-identified data for those recently treated with a biologic as part of usual care. Physicians (rheumatologists) were screened for duration of practice (3-30yrs) and patient volume (incl. >5 AS biologic patients/month) and recruited from a large panel to be geographically representative. Eligible patient charts (≥3) were randomly selected from a sample of patients visiting each center/practice during the screening period. Physicians abstracted patient diagnosis, treatment patterns/dynamics and patient symptomatology/disease status/outcomes. Patients on adalimumab/